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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,837	08/26/2003	Robert J. Sweeney	279.648USI	3849
21186 7590 08/15/2007 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER FLORY, CHRISTOPHER A	
			ART UNIT 3762	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/648,837

Applicant(s)

SWEENEY ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 and 40-48 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 June 2007 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 12 June 2007 with respect to the rejection of claims 1-6 and 16-17 under 35 U.S.C. §102(b) as being anticipated by Siegel have been fully considered but they are not persuasive. Claims 1-6 and 16-17 stand rejected for the arguments made of record in the Office Action filed 12 February 2007 and restated in the paragraphs below.

Applicant argues that Siegel fails to disclose that the swellable member changes to an extent such that it is capable of being detected by acoustic energy since the housing will inhibit acoustic energy transmission. Examiner maintains the position that the change in size due to swelling will inherently be detectable by the use of acoustic energy, such as medical ultrasound in the range of 10-15MHz which provides high axial and lateral resolution. It is also a reasonable assertion that ultrasound will be able to detect said changes through a housing. Furthermore, in view of the apparatus claims, it

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is not necessary for the prior art to expressly disclose a limitation such as the one being argued, but rather need only be *capable of* producing said result. Since it is held that the disclosure of Siegel provides a member capable of swelling to a size detectable by acoustic energy, the rejection under 35 U.S.C. §102(b) is deemed proper. The requested supporting documents are provided in Hood (US 5,324,297) and Kaplan (US 6,770,032).

Applicant further argues that the swellable member of Siegel cannot contact tissue since it is located within a housing. However, the Siegel abstract clearly states that the housing is open such that the swellable member may contact body fluids, and it is therefore considered to be capable of contacting body tissue as well.

3. Applicant's arguments filed 17 July 2006 with respect to the rejection of claims 1-33, 35, 36, 38 and 40-46 as being unpatentable over Altman et al. v. Lew et al., f.i.v. Siegel have been fully considered but they are not persuasive. Claims 1-17, 19-33, 35, 36, 38 and 43-46 stand rejected for the arguments made of record in the Office Action filed 12 February 2007 and restated herein.

Applicant argues that none of Altman, Lew or Siegel discloses a swellable member that will change to an extent that would be capable of being detected by acoustic energy with adequate signal-to-noise ratio. Examiner maintains that this is identically the function of the device disclosed in the Lew et al. reference (ABSTRACT; Figs. 2, 11, 16,17). Applicant also argues that Altman does not indicate locating a hydrogel within a myocardium. However, this is explicitly stated in the cited portions of the reference, so no further explanation is deemed necessary. Furthermore, even if

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such a feature were not disclosed, the device of the rejecting reference need only be *capable of* locating a hydrogel within a myocardium. It is held that Altman, Lew, and Siegel are all capable of such a location for the swellable member.

Applicant argues that Lew does not suggest or disclose using acoustic energy to detect a physiological condition based on a change in a physical parameter of the hydrogel. It is maintained that all of these limitations are disclosed within the abstract of the Lew reference, wherein the presence of the detected analyte or the analyte concentration is considered the physiological condition.

4. Applicant's arguments with respect to claims 18 and 40-42 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6 and 16-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Siegel (U.S. Patent No. 5,062,841).

Siegel teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swellable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swellable member swells in response to an increase in blood glucose level (col. 3 lines 51-56) and that the swellable member is disclosed as, or inherently capable of, implantation in contact with the tissue since it is disclosed as being in a housing open such that it can contact body fluids (abstract). In regards to claims 1 and 2, Examiner takes the position that the hydrogel membrane as taught by Siegel has at least one physical property (swelling) that changes in response to a physiological condition (an increase in blood glucose level). Further, Examiner takes the position that change in size due to swelling, is inherently detectable by use of acoustic energy. Factual support for this assertion can be found in Hood (US 5,324,297) and Kaplan (US 6,770,032). Since Hood'297 discloses that ultrasound can be delivered at an energy so as to cut through a PMMA housing, it is clear that ultrasound could also be provided at a lower energy so as to leave the housing in tact but nonetheless be sufficient of energy to provide imaging resolution to monitor the change of size of the swellable member of Siegel. Kaplan'032 teaches of using ultrasound imaging to project through the front surface of a housing and sensing the diminished by still present signal reflected from the back portion of the housing. Since the ultrasound is able to detect the signal from the rear-facing portion of this housing, it is supported that it could also distinguish the signal created by a material placed there between, albeit a small signal, such as from the swellable member of Siegel.

In regards to claims 3-6, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size.

7. Claims 1-7, 10-17, 19-29, 37, 43 and 46 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lew et al. (US 2003/0100822, hereinafter Lew'822).

Lew'822 is considered to disclose the invention as claimed substantially in the title, abstract, and Figures 1, 2, 7A, 10A, 11-13, 15-17 and their supporting paragraphs.

8. Claims 1-33, 36-38 and 40-46 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Slepian (US 2002/0176849, hereinafter Slepian'849).

Slepian'849 is considered to disclose the limitations of the rejected claims substantially in the abstract, Figures 2, 4, 5B and their supporting paragraphs.

9. Claims 1-8, 10-12, 16-30, 33, 37, 38, 40, 41, 43 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Unger et al. (US 6,123,923, hereinafter Unger'923).

Unger'923 is considered to disclose the limitations of the rejected claims substantially in the abstract, Figures 3-5, 8, 9 and their supporting paragraphs.

10. Claims 18, 19, 34, 40, 42, 43, 47 and 48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sutton et al. (US 6,348,186, hereinafter Sutton'186).

Sutton'186 is considered to disclose the claimed invention substantially in the abstract, Figure 1 and supporting paragraphs, and the Background of the Invention (specifically column 11, lines 55-67).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-17, 19-33 35, 36, 38, and 43-46 stand rejected, under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630) in view of Lew et al. (U.S. 2003/0100822), and further in view of Siegel (U.S. Patent No. 5,062,841) as applied above.

Altman et al. teaches of an implantable cardiac drug delivery system for delivery agents to be introduced within the myocardium of a subject (col. 9 lines 32-35), comprising a delivery patch or patches that may consist of a hydrogel (col. 12 lines 11-13), a catheter (col. 7 lines 56-61), and the use of an acoustic transmitter (col. 20 lines 39-43). The Altman et al. reference does not specifically teach that hydrogels are commonly known in the art to be pH and/or ion sensitive, nor does the Altman et al. reference teach that hydrogels are commonly known in the art to swell in response to a physiological condition.

Lew et al. teaches that hydrogels, including pH sensitive hydrogels, are well known in the art for being used as protective biocompatible coating for implantable devices, and are further defined as polymeric materials that swell in water and other fluids (paragraphs 7 and 9).



Siegel teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swallowable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swallowable member swells in response to an increase in blood glucose level (col. 3 lines 51-56).

In regards to claim 1, Examiner takes the position that hydrogel membrane that makes of the patch as taught by Altman et al. would be inherently capable of having at least one physical property change (swelling in size) in response to a physiological condition, such as an increase in blood glucose level since it is known that hydrogels have the characteristic, as taught by Siegel (col. 3 lines 51-56).

In regards to claims 3-6 and 22-29, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size. In the alternative, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Altman et al. to include hydrogels that are capable of swelling as taught by both Lew et al. and Siegel, since the hydrogels as taught by both Lew et al. and Siegel are well known in the art for being biocompatible membranes.

In regards to claims 8 and 30, Examiner takes the position that implantable membrane could be of any shape, including spherical, and would be a matter of design choice. In regards to claims 18, Altman et al. teaches that of the use of multiple patches (70 and 75) that have membranes, which may comprise a hydrogel (col. 12 lines 11-13).

In regards to 12-15, Examiner takes the position that the Altman et al. reference inherently teaches of the use of a display, user interface and an external programmer, since the ultrasound transducer is being used in connection with ultrasound imaging (col. 20 lines 39-42). Examiner also takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system to include use of a computer network in connection with the user interface, since it is well known in the art to use a network for enhanced feedback and communication of detected results.

Further in regards to claim 19, the limitations of the claim are clearly anticipated by Lew et al. in the Abstract, as well as Figures 2, 11, 16 and 17.

Regarding claim 38, Altman et al. discloses a body sized and shaped to be introduced within a vein or artery (column 9, lines 55-66; column 11, lines 24-39).

Regarding claim 43, an implantable medical device including a state that is altered using a change in the physical property is disclosed both by Siegel (ABSTRACT) and by Lew et al. (ABSTRACT, where the hydrogel is considered the IMD which alters its size in response to the change in analyte concentration adjacent to it).

Regarding claims 36, 44 and 45, Altman et al. discloses an implantable medical device including an intravascular lead with an acoustic transducer (column 27, lines 13-44).

Regarding claim 46, Siegel discloses modifying a therapy using the detected change in the physiological condition (ABSTRACT).

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13. Claims 34, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lew'822, Slepian'849 or Unger'923, each in view of Sutton'186.

Lew'822, Slepian'849 and Unger'923 each disclose the invention substantially as claimed in claims 19 and 43 including swellable ultrasound contrasting agents that have a physical characteristic change detected by ultrasound, but do not expressly disclose that that which is detected thereby is ischemia. In the same field of endeavor, Sutton'186 discloses that ultrasound contrast agents can serve to enhance echoes from arterial blood for the detection of ischemia (column 11, lines 55-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify any of Lew'822, Slepian'849 or Unger'923 to detect ischemia, since Sutton'186 teaches that ultrasound agents such as those disclosed in each of those references can be used to detect ischemia when placed in arterial blood.

#### ***Allowable Subject Matter***

14. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vilkomerson et al. (US 5,161,536) discloses a system for locating

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and visually displaying a biocompatible catheter inserted in an artery via ultrasonic imaging.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

14 August 2007

**/George Manuel/**  
Primary Examiner